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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/929,597	08/13/2001	Todd K. Whitehurst	AB-126U	9184

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EXAMINER

MACHUGA, JOSEPH S

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 09/15/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/929,597

Applicant(s)

WHITEHURST ET AL.

Examiner

Joseph S. Machuga

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 and 3. 6) ☐ Other:

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 3 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 3 "greater than about 100-150Hz" is indefinite. It is unclear whether values such as 125hz or 99hz would meet this limitation. Similar problems exist with claim 5.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 6, 13-16 and 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al (WO98/37926.)
4. It is considered obvious to use this device to stimulate the nerves at or near the spine given the disclosure on page 6 lines 10-15 stating to relieve or reduce pain the stimulator can be used to stimulate nerves and associated neural pathways.

5. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al (WO98/37926) Silverstone #6161044.

6. Schulman et al discloses an implantable micro-stimulator system used to decrease pain. The system includes one or more nerve stimulators implanted adjacent a selected nerve. The system can also include at least one implantable sensor that senses a physical property of the patient and then provides appropriate feedback to an external device. Not disclosed by this reference is the specific region of the spine; that is, either the Lissauer's tract, the ventral commissure or the spinothalamic tract as recited in claim 2.

7. Silverstone teaches that the spinothalamic tract is a know pathway for pain impulses and that stimulation along the pathways that carry those impulses can relieve pain (column 1, lines 58-67 and column 2 lines 1-10.)

8. It would have been obvious to one of ordinary skill in the art to place a nerve stimulator in Schulman et al's system adjacent the spinothalamic tract to reduce pain as taught by Silverstone.

9. Claims 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al (WO98/37926) in view of Zilber.

10. Schulman et al discloses an implantable micro-stimulator system used to decrease pain. The system includes one or more nerve stimulators implanted adjacent a selected nerve. The system can also include at least one implantable sensor that senses a physical property of the patient and then provides appropriate feedback to an

external device. Not disclosed by this reference is the frequency and location of the implant.

11. Zilber discloses an implant placed adjacent to the dorsal region of the spinal cord. The reference teaches that a frequency of 5-200 Hz is effective in reducing pain.

12. Given this teaching, it would have been obvious to one of ordinary skill in the art to place a stimulator adjacent the dorsal region of the spinal cord and operate it at a frequency of 5-200 Hz given Zilber's teaching that this helps reduce pain. The frequency as recited in method claims 3 and 5 are considered provided for by this reference since the range taught by this reference is both above 150 Hz and below 100 Hz.

13. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al (WO98/37926) in view of King (6058331.)

14. Schulman et al discloses an implantable micro-stimulator system used to decrease pain. The system includes one or more nerve stimulators implanted adjacent a selected nerve. The reference does not teach placing the stimulator adjacent the C5, C6, C7, C8 or T1 nerve fibers to relieve pain in the arm or next to the L1-L5, S1 or S2 to relieve pain in the legs.

15. King teaches that it is old and well know to place a stimulator next to the T8-L1 nerves to relieve pain in the feet or legs and next to the C5-C8 to relieve pain in the arms or hands (note column 5, lines 20+.)

16. Given this teaching it would have been obvious to one of ordinary skill in the art to place a stimulator implant in Schulman et al's device next to the T1-L1 nerves to relieve pain in the legs or feet, or next to the C5-C8 nerves to relieve pain in the arms or hands.

17. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al (WO98/37926) in view of Feler et al (6002964.)

Schulman et al discloses an implantable micro-stimulator system used to decrease pain. The system includes one or more nerve stimulators implanted adjacent a selected nerve. The reference does not teach placing the stimulator adjacent the T10-T12, L1-L5 or S1-S5 to relieve pain in the pelvic region, or next to the T1-T12, L1-L5 or S1 to relieve pain in the back.

18. Feler et al teaches that it is old and well know to place a stimulator next to the T10 -T12 nerves to reduce pain in the back or the pelvic region.

19. Given this teaching it would have been obvious to one of ordinary skill in the art to place a stimulator implant in Schulman et al's device next to the T10-T12 regions to relieve pain in the back or pelvic regions.

20. Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al (WO98/37926) in view of MacDonald et al (#5776170.)

21. Schulman et al discloses an implantable micro-stimulator system used to decrease pain. The system includes one or more nerve stimulators implanted adjacent a selected nerve. The reference does not teach placing the stimulator adjacent either the C2-C5 nerve fibers to relieve pain in the cervical region or next to the C1-C8 region to relieve pain in the head or neck.

22. MacDonald et al teaches that it is old and well known to place a stimulator next to the C1-C8 nerves to relieve pain in the neck or head or cervix region (see column 3, lines 40-48.)

23. Given this teaching it would have been obvious to one of ordinary skill in the art to place a stimulator implant in Schulman et al's device next to the C1-C8 regions to relieve pain in the head, neck or cervix regions.

Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al (WO98/37926) in view of Schulman et al (5358514.)

24. Schulman et al discloses an implantable micro-stimulator system used to decrease pain. The system includes one or more nerve stimulators implanted adjacent a selected nerve. Not disclosed by this reference is the size of the implant as recited in the claims. Schulman et al (514) discloses that the implant should be around 10mm in length. Also, viewing Figures 1A, 1B and 1C if the implant is approximately 10 mm in

length then the leads would be less than 150mm and within 150 mm of the nerve to be stimulated.

25. To make the implants in Schulman et al's (WO 98/37926) device around 10mm and with leads in proportion to that and locate the device within 150mm of the nerve as disclosed by Schulman (514) would have been obvious would have been obvious to one of ordinary skill in the art since the smaller the device the easier it would be to implant.

26. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al (WO 98/37926) in view of Schulman et al (#5358514) as applied to claim 18 above, and further in view of Silverstone.

27. Silverstone teaches that the spinothalamic tract is a known pathway for pain impulses and that stimulation along the pathways that carry those impulses can relieve pain (column 1, lines 58-67 and column 2 lines 1-10.)

28. Given this teaching, it would have been obvious to one of ordinary skill in the art to place a nerve stimulator in Schulman et al's system adjacent the spinothalamic tract to reduce pain as taught by Silverstone.

29. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph S. Machuga whose telephone number is 703-305-6184. The examiner can normally be reached on Monday-Friday; 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.



Joseph S. Machuga
Examiner
Art Unit 3762



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